



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-1046]

Specific Listing for 1-boc-4-AP, a Currently Controlled List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is establishing a specific listing and DEA Chemical Control Number for *tert*-butyl 4-(phenylamino)piperidine-1-carboxylate (also known as 1-boc-4-AP; and CAS Number: 125541-22-2) and its salts as a list I chemical under the Controlled Substances Act. Although 1-boc-4-AP is not specifically listed as a list I chemical of the Controlled Substances Act with its own unique Chemical Control Number, it has been regulated as a list I chemical in the United States since May 15, 2020, as a carbamate of *N*-phenylpiperidin-4-amine, a list I chemical. Therefore, DEA is simply amending the list I chemicals list in its regulations to include a separate listing for 1-boc-4-AP, a currently controlled list I chemical.

DATES: Effective date [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

tert-Butyl 4-(phenylamino)piperidine-1-carboxylate (also known as 1-boc-4-AP) is a chemical that is structurally related to *N*-phenylpiperidin-4-amine (also known as *N*-phenyl-4-piperidinamine, 4-anilinopiperidine, and 4-AP). *N*-Phenylpiperidin-4-amine, including its amides, its carbamates, and its salts, is listed as a list I chemical at 21 CFR 1310.02(a). See 85

FR 20822 (April 1, 2020) (effective May 15, 2020). The chemical structure of 1-boc-4-AP defines it as a carbamate of *N*-phenylpiperidin-4-amine. Accordingly, under 21 CFR 1310.02(b), 1-boc-4-AP, as a carbamate of *N*-phenylpiperidin-4-amine, is and continues to be a regulated list I chemical.¹

Legal Authority

The Controlled Substances Act (CSA) and the Drug Enforcement Administration's (DEA) implementing regulations give the Attorney General, as delegated to the Administrator of DEA (Administrator), the authority to specify, by regulation, a chemical as a "list I chemical."² This term refers to a chemical that is used in manufacturing a controlled substance in violation of subchapter I (Control and Enforcement) of the CSA and is important to the manufacture of the controlled substance.³ The current list of all list I chemicals is available in 21 CFR 1310.02(a).

In addition, the United States is a Party to the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention), December 20, 1988, 1582 U.N.T.S. 95. Under Article 12 of the 1988 Convention, when the United States receives notification that a chemical has been added to Table I or Table II of the 1988 Convention, the United States is required to take measures it deems appropriate to monitor the manufacture and distribution of that chemical within the United States and to prevent its diversion, including measures related to international trade.

Background

In a letter dated May 27, 2022, the United Nations Office on Drugs and Crime, in accordance with Article 12, paragraph 6 of the 1988 Convention, informed the Permanent Mission of the United States of America to the United Nations (Vienna) that the Commission on Narcotic Drugs (CND) decided to place the chemical 1-boc-4-AP in Table I of the 1988

¹ *N*-phenylpiperidin-4-amine, including its amides, its carbamates, and its salts, has been subject to list I chemical regulations since May 15, 2020, pursuant to a final rule (April 15, 2020; 85 FR 20822).

² 21 U.S.C. 802(34) and 871(b) and 21 CFR 1310.02(c).

³ 21 U.S.C. 802(34) and 21 CFR 1300.02(b).

Convention (CND Dec/65/5) at its 65th Session on March 16, 2022. As discussed above in this final rule, 1-boc-4-AP – by virtue of being a carbamate of *N*-phenylpiperidin-4-amine – has been regulated as a list I chemical of the CSA since May 15, 2020.⁴ Therefore, all regulations and criminal sanctions applicable to list I chemicals have been and remain applicable to 1-boc-4-AP.

Effect of Action

As discussed above, this rule does not affect the continuing status of 1-boc-4-AP as a list I chemical in any way. This action, as an administrative matter, merely establishes a separate, specific listing for 1-boc-4-AP in list I of the CSA and assigns a DEA chemical control number for the substance. This action will allow DEA to effectively monitor regulated transactions of 1-boc-4-AP, including the manufacture, distribution, importation, or exportation of 1-boc-4-AP, and to provide accurate reporting to the International Narcotics Control Board.

Chemical Mixtures of 1-boc-4-AP

Pursuant to the final rule published on April 15, 2020,⁵ chemical mixtures containing 1-boc-4-AP have been and continue to be subject to regulatory requirements at any concentration – unless a manufacturer submits to DEA an application for exemption of a chemical mixture, DEA accepts the application for filing, and DEA exempts the chemical mixture in accordance with 21 CFR 1310.13 (Exemption of chemical mixtures by application).

Since even a small amount of 1-boc-4-AP can potentially yield a significant amount of controlled substances, DEA believes that the continued regulation of chemical mixtures containing any amount of 1-boc-4-AP as a list I chemical is necessary to prevent its illicit extraction, isolation, and use. 1-boc-4-AP is already subject to domestic control under list I as a carbamate of *N*-phenylpiperidin-4-amine, and DEA’s current regulations provide that a chemical mixture containing any amount of *N*-phenylpiperidin-4-amine is a List I chemical. As a technical, conforming change in connection with the separate listing of 1-boc-4-AP, this rule

⁴ 85 FR 20822 (April 15, 2020).

⁵ 85 FR 20822.

modifies the “Table of Concentration Limits” in 21 CFR 1310.12(c) to reflect that a chemical mixture containing any amount of 1-boc-4-AP is subject to CSA chemical control provisions, including 21 CFR parts 1309, 1310, 1313, and 1316. No additional requirements are being imposed.

DEA has implemented an application process to exempt certain chemical mixtures from the requirements of the CSA and its implementing regulations.⁶ Manufacturers may submit an application for exemption for those mixtures that do not meet the criteria set forth in 21 CFR 1310.12(d) for an automatic exemption. Pursuant to 21 CFR 1310.13(a), DEA may grant exempt status to a chemical mixture by publishing a final rule in the *Federal Register*, if DEA determines that: 1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance, and 2) the listed chemical or chemicals cannot be readily recovered.

Requirements for Handling List I Chemicals

The listing of 1-boc-4-AP as a list I chemical continues to subject handlers (manufacturers, distributors, importers, and exporters) and proposed handlers to all of the regulatory controls and administrative, civil, and criminal actions applicable to the manufacture, distribution, importation, and exportation of a list I chemical. Since May 15, 2020, persons handling 1-boc-4-AP, including regulated chemical mixtures containing 1-boc-4-AP, have been required to comply with list I chemical regulations, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, or exports), or proposes to engage in such handling, of 1-boc-4-AP or a chemical mixture containing 1-boc-4-AP, must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, and 958. Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309.

⁶ 21 CFR 1310.13.

2. *Records and Reports.* Every DEA registrant must maintain records and submit reports to DEA with respect to 1-boc-4-AP pursuant to 21 U.S.C. 830 and in accordance with 21 CFR 1310. Pursuant to 21 CFR 1310.04, a record must be made and maintained for two years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

3. *Importation and Exportation.* All importation and exportation of 1-boc-4-AP must be done in compliance with 21 U.S.C. 957, 958, and 971 and in accordance with 21 CFR part 1313.

4. *Security.* All applicants and registrants must provide effective controls against theft and diversion in accordance with 21 CFR 1309.71–1309.73.

5. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, or otherwise dispose of a list I chemical or where records relating to those activities are maintained, are controlled premises as defined in 21 U.S.C. 880(a) and 21 CFR 1316.02(c). The CSA allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A.⁷

6. *Liability.* Any activity involving 1-boc-4-AP not authorized by, or in violation of, the CSA is unlawful, and would subject the person to administrative, civil, and/or criminal action.

REGULATORY ANALYSES

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest.

⁷ 21 U.S.C. 880.

As discussed above, 1-boc-4-AP is currently and continues to be regulated as a list I chemical as a carbamate of *N*-phenylpiperidin-4-amine.

Pursuant to 5 U.S.C. 553(b)(3)(B), DEA finds that notice and comment rulemaking is unnecessary and that good cause exists to dispense with these procedures. The addition of a separate listing for 1-boc-4-AP and its DEA chemical control number in the list of list I chemicals in 21 CFR 1310.02(a) makes no substantive difference in the status of this chemical as a list I chemical, but instead is “a minor or merely technical amendment in which the public is not particularly interested.” *National Nutritional Foods Ass’n v. Kennedy*, 572 F.2d 377, 385 (2d Cir. 1978) (quoting S. Rep. No. 79-752, at 200 (1945)). See also *Utility Solid Waste Activities Group v. E.P.A.*, 236 F.3d 749, 755 (D.C. Cir. 2001) (the “unnecessary” prong “is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public”) (internal quotations and citation omitted). This rule is a “minor” or “technical” amendment to 21 CFR 1310 as it is “insignificant in nature and impact, and inconsequential to the industry and public.” Therefore, publishing a notice of proposed rulemaking and soliciting public comment are unnecessary.

In addition, because 1-boc-4-AP is already subject to domestic control under list I as a carbamate of *N*-phenylpiperidin-4-amine and no additional requirements are being imposed through this action, DEA finds good cause exists to make this rule effective immediately upon publication in accordance with 5 U.S.C. 553(d)(3). DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of 1-boc-4-AP. 1-boc-4-AP is currently regulated as a list I chemical, and this level of control does not change with this rulemaking.

Executive Orders 12866 and 13563, Regulatory Planning and Review and Improving Regulation and Regulatory Review

This rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. This rule is not a significant regulatory action under E.O. 12866. 1-boc-4-AP

is already regulated as a list I chemical in the United States, as a carbamate of the list I chemical *N*-phenylpiperidin-4-amine. In this final rule, DEA is merely making an administrative change by amending its regulations to separately list 1-boc-4-AP as a list I chemical and to assign the DEA chemical control number 8336 to this chemical. A separate listing for 1-boc-4-AP will not alter the status of 1-boc-4-AP as a list I chemical. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) applies to rules that are subject to notice and comment under section 553(b) of the APA or other laws. As noted in the above section regarding the applicability of the APA, DEA determined that there is good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply.

Unfunded Mandates Reform Act of 1995 (UMRA)

In accordance with the UMRA, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this rule will not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.” Therefore, neither a Small Government Agency Plan nor any other action is required under the UMRA.

Paperwork Reduction Act

The action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501-3521. This action will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects 21 CFR Part 1310

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, DEA amends 21 CFR part 1310 as follows:

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES

1. The authority citation for 21 CFR part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

2. In § 1310.02, add reserved paragraph (a)(38) and paragraph (a)(39) to read as follows:

§ 1310.02 Substances covered.

* * * * *

(a) * * *

(38) [Reserved]

(39) 1-boc-4-AP (*tert*-butyl 4-(phenylamino)piperidine-1-carboxylate) and its salts

.....8336

* * * * *

3. In § 1310.04:

a. Redesignate paragraphs (g)(1)(iii) through (xviii) as paragraphs (g)(1)(iv) through (xix), respectively; and

b. Add new paragraph (g)(1)(iii).

The addition reads as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

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(iii) 1-boc-4-AP (*tert*-butyl 4-(phenylamino)piperidine-1-carboxylate) and its salts.

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4. Section 1310.12 is amended by adding in alphabetical order in the table in paragraph (c) an entry for 1-boc-4-AP (*tert*-butyl 4-(phenylamino)piperidine-1-carboxylate) and its salts to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

DEA chemical code number	Concentration	Special conditions
List I Chemicals		
* * * * *		
1-boc-4-AP (<i>tert</i> -butyl 4-(phenylamino)piperidine-1-carboxylate) and its salts	8336 Not exempt at any concentration	Chemical mixtures containing any amount of 1-boc-4-AP (<i>tert</i> -butyl 4-(phenylamino)piperidine-1-carboxylate) and its salts are not exempt
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Signing Authority

This document of the Drug Enforcement Administration was signed on November 1, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an

official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Scott Brinks,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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